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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte RICHARD J. LAZZARA, THOMAS S. HEYLMUN, and
KEITH D. BEATY

Appeal 2010-001766
Application 09/237,605
Technology Center 3700

Before JENNIFER D. BAHR, LINDA E. HORNER, and
EDWARD A. BROWN, *Administrative Patent Judges*.

HORNER, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Richard J. Lazzara et al. (Appellants)¹ seek our review under
35 U.S.C. § 134 of the Examiner's decision rejecting claims 51 and 60-75.

¹ Appellants identify the real party-in-interest as Biomet 3i, LLC. App.
Br. 3.

An oral hearing was held on January 19, 2012. We have jurisdiction under 35 U.S.C. § 6(b). We AFFIRM-IN-PART.

THE INVENTION

Appellants' claimed invention "relates to dental implants intended for insertion in a hole provided in living jawbone for eventual support of artificial teeth." Spec. 1, ll. 6-7. Claim 51, reproduced below, is representative of the subject matter on appeal.

51. A dental implant made of titanium metal, comprising:
- a smooth head portion for receiving a dental restoration component;
 - a lowermost end opposing said head portion;
 - a threaded portion for engaging bone between said head portion and said lowermost end; and
 - a roughened region for facilitating osseointegration with said bone located on said threaded portion and extending to said lowermost end of said implant, said roughened region being uniformly acid etched with a second acid solution after a native oxide layer had been removed by contact with a first acid solution with minimum consumption of said titanium metal, said roughened region including an array of irregularities having peak-to-valley heights not greater than about 10 microns.

Independent claims 63 and 68 are directed to a titanium dental implant having a threaded portion with an acid-etched surface, "said acid-etched surface having an array of irregularities having peak-to-valley heights not greater than about 10 microns, said irregularities including cone-shaped elements."

THE EVIDENCE

The Examiner relies upon the following evidence:

Niznick	US 5,571,017	Nov. 5, 1996
Haruyuki	JP 3-146679 A2	Jun. 21, 1991
Ann Wennerberg et al., <i>Design and Surface Characteristics of 13 Commercially Available Oral Implant Systems</i> , 8 INT'L J. OF ORAL & MAXILLOFACIAL IMPLANTS, 622-633 (1993).		

Appellants provide the following declaratory evidence:

Declaration Under 37 C.F.R. § 1.132 of Dr. Prabhu Gubbi, submitted on June 26, 2003.

Declaration Under 37 C.F.R. § 1.132 of Dr. Stephan S. Porter, submitted on April 29, 2002.

THE REJECTION

Appellants seek review of the Examiner's rejection of claims 51 and 60-75 under 35 U.S.C. § 103(a) as unpatentable over Haruyuki or Wennerberg in view of Niznick.

ISSUES

The issues presented by this appeal are:

Did the Examiner provide adequate reasoning based on rational underpinnings to explain why one of ordinary skill in the art would have been led to apply the surface treatment method of Haruyuki to the dental implant of Niznick?

Would the surface treatment method of Haruyuki, when applied to the dental implant of Niznick, result in a "roughened region including an array of irregularities having peak-to-valley heights not greater than about 10 microns" as called for in claim 51?

Does the evidence in support of non-obviousness outweigh the evidence in support of obviousness for claim 51?

Would the surface treatment method of Haruyuki, when applied to the dental implant of Niznick, result in a roughened region or an acid-etched surface that is structurally similar to the region or surface that results from the two-step method of removing a native oxide layer and then acid-etching using a mixture of sulfuric and hydrochloric acids, as called for in claim 61?

Did the Examiner present a prima facie case to show that the surface treatment method of Haruyuki, when applied to the dental implant of Niznick, would result in “irregularities including cone-shaped elements” as called for in claims 63 and 68?

FINDINGS OF FACT

1. Haruyuki discloses “body restoration parts made of titanium or titanium-based alloys in the dental or surgical field, particularly for improving implant parts such as artificial joints, bone connecting parts, artificial bone, artificial dental roots and dentures.” Haruyuki 2: Technical application field.²
2. In particular, Haruyuki discloses at least the surface of the embedded portion of the body restoration part is acid treated to provide random pits having mean pore size of 1-10 μm and mean depth of 0.5 to 5 μm . Haruyuki 3: Means to solve the problems.

² References to Haruyuki refer to the English-language translation PTO 06-6791, dated September 2006, attached as Exhibit 5 to the Appeal Brief.

3. Haruyuki discloses that “in case of using a rough surface having unevenness, the bone can penetrate and grow in fine pits, achieving a micro-anchoring effect and resulting in strong support of the parts in the bone” and “the required strong initial connecting strength can be obtained at a relatively early stage.” Haruyuki 2: Detailed explanation of the invention.
4. Haruyuki discloses a two-step acid etching process, which includes a pre-treatment step, in which the surface of the embedded portion is immersed in 1 to 6 weight% aqueous hydrofluoric acid (HF) solution for 30 seconds to 3 minutes to remove the oxide film on the surface and furnish micro fine pits, followed by a post-treatment comprising immersing the portion for 10 to 60 seconds in a mixed aqueous solution of 1 to 6 weight% aqueous hydrofluoric acid solution and 1 to 10 weight% hydrogen peroxide (H_2O_2) solution. Haruyuki 3: Means to solve the problems; and Haruyuki 3: Effect.
5. Haruyuki discloses that “if [the mean pore depth] is greater than 5 μm , sharp edges or pointed ends will form on the ridgelines of the pits which can irritate the tissues (may develop to become a trigger for cancer).” Haruyuki 3-4: Effect.
6. Haruyuki teaches that “[t]he post-treatment immersion in mixed aqueous solutions of HF and H_2O_2 is to smooth the sharp edges or pointed ends formed on the ridgelines of the micro fine pits generated during the pretreatment.” Haruyuki 3-4: Effect.

7. Niznick discloses “externally-threaded, endosseous dental implants with generally cylindrical-shaped bodies and self-tapping threads at or near the distal end of the implant.” Niznick, col. 4, ll. 14-16.
8. Niznick discloses that the external surface of the threaded distal end of the implant is “preferably uncoated and has a smooth enough surface to maintain sharp cutting threads for self-tapping insertion,” preferably having a peak-to-valley distance of up to 20 microns. Niznick, col. 4, ll. 44-47, col. 5, ll. 16-19.
9. Niznick discloses that the external surface of the middle, preferably threaded, portion of the implant is roughened or coated, or both, to increase the percentage of the surface in contact with bone, thus enabling the implant to better withstand biting forces, preferably with an average peak-to-valley distance of 25 microns or greater. Niznick, col. 4, ll. 48-52, col. 5, ll. 19-22.
10. Appellants submitted a Declaration of Prabhu Gubbi (“Gubbi Decl.”) in which Dr. Gubbi states:

At the request of *3i*’s attorneys, I have carried out certain inspections of commercially pure titanium implants after they have been exposed to various treatments and compared the results with those of the methodology in the subject patent application, which is owned by *3i*. The results of this work are discussed below. In one series of tests (Exhibit A), a titanium dental implant was given a treatment according to the method described in this patent application to produce an Osseotite® surface, which is commercially available on *3i*’s dental implants. In the second series of tests (Exhibit B), titanium implants were exposed to the two-step procedure

described in a Japanese published patent application, JP 3146679 A2 to Haruyuki.

App. Br., Exhibit 8, Gubbi Decl., para. D.

11. Dr. Gubbi states that the titanium dental implant of Exhibit A was immersed in hydrofluoric acid to remove the native oxide layer and was subsequently immersed in a mixture of hydrochloric acid and sulfuric acid to produce an Osseotite® surface. Gubbi Decl., para. E.
12. Dr. Gubbi concluded that “the treatments of [Haruyuki] produced surfaces that do not resemble the [Osseotite®] surface achieved by the methodology of the subject patent application, as shown in Exhibit A.” Gubbi Decl., para. H.
13. Appellants submitted a Declaration Under 37 C.F.R. § 1.132 of Dr. Stephan S. Porter (“Porter Decl.”) which provides evidence of asserted commercial success of dental implants having an Osseotite® surface prepared in accordance with a two-step, acid-etch treatment wherein the native oxide layer is substantially removed via hydrofluoric acid and the resultant surface is etched with a combination of sulfuric and hydrochloric acids. Porter Decl., paras. 2-8.

ANALYSIS

Claims 51, 60, and 62

Appellants argue claims 51, 60, and 62 as a group. App. Br. 13. We select claim 51 as representative, and claims 60 and 62 stand or fall with

claim 51. *See* 37 C.F.R. § 41.37(c)(1)(vii) (2011). Appellants present separate arguments for dependent claim 61, which we address *infra*.

We must first construe the claim before we determine whether the prior art renders the claimed subject matter obvious. *Medichem, S.A. v. Rolabo, S.L.*, 353 F.3d 928, 933 (Fed. Cir. 2003). Independent claim 51 is directed to a dental implant made of titanium metal³ comprising a threaded portion having a roughened region being uniformly acid etched and “including an array of irregularities having peak-to-valley heights not greater than about 10 microns.” Because the claim calls for an implant “comprising” a roughened region “including” an array of irregularities having a specified peak-to-valley height, we construe the claim not to require every irregularity to be less than or equal to 10 microns. Rather, the language of claim 51 is broad enough to encompass an array of irregularities of the specified topography and additional irregularities having peak-to-valley heights greater than 10 microns.⁴

³ We understand “titanium metal” to refer to commercially pure titanium and not to be so broad as to encompass titanium alloy. *See* Oral Hearing Transcript 2-4. *See also* Application 10/843,916 (‘916 Application), also owned by Biomet 3i, LLC, in which Appellants describe that “while a consistent response to the two-step acid treatment is obtained on commercially pure titanium, the same treatment process produces non-uniform results on titanium alloys.” ‘916 Application at 4, ll. 1-3.

⁴ *See* Oral Hearing Transcript at 8, ll. 14-22:

JUDGE BROWN: Does your claim require that each one of those irregularities have that peak to valley height? Some of them? How do you interpret that?

Further, the roughened region, in addition to being defined by the array of irregularities having specified peak-to-valley heights, is also defined by the process by which the roughened region is achieved, i.e., by a two-step acid etching process. Thus, the claim contains a product-by-process limitation. “A product-by-process claim is ‘one in which the product is defined at least in part in terms of the method or process by which it is made.’” *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1315 (Fed. Cir. 2006) (quoting *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 158 (1989)). The claim is directed to the ultimate product, not the underlying process. *See id.* at 1317 (“Regardless of how broadly or narrowly one construes a product-by-process claim, it is clear that such claims are always to a product, not a process.”). “Once a product is fully disclosed in the art, future claims to that same product are precluded, even if that product is claimed as made by a new process.” *Id.* at 1315. Thus, “[i]f the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985) (citations omitted). In other words, “[t]he patentability of a

MS. BAIO: The claim says having peak and valley heights -- it just says the roughened region includes an array of irregularities having peak-to-valley heights not greater than 10 microns.

JUDGE BROWN: So it could include peaks that don't have that?

MS. BAIO: I think it could. I just think it's probably a majority would be less than 10 microns -- the vast majority.

product does not depend on its method of production.” *SmithKline*, 439 F.3d at 1317.

The Examiner treated the acid etching steps of this claim as product-by-process limitations and stated that:

since a similar type of etching process is used to form irregularities on the surface of the same material as claimed that the surface irregularities of Haruyuki, that Haruyuki’s surfaces would inherently be substantially the same as those set forth in the claims; i.e. cone-shaped and/or spaced about the prescribed distance.

Ans. 5.

Haruyuki discloses a two-step acid etching process that falls within the broad process recited in claim 51⁵ performed on a titanium dental implant resulting in a surface having pores with a mean depth of 0.5 μm to 5 μm (Facts 2, 4). Given that Haruyuki’s pores have an average depth below 10 microns, we find by a preponderance of the evidence that Haruyuki discloses a roughened surface including an array of irregularities having peak-to-valley heights not greater than about 10 microns. We further find that based on the breadth of claim 51, which is not limited to specific first and second acid solutions, the Examiner reasonably concluded by a preponderance of the evidence that Haruyuki’s roughened surface would be

⁵ Claim 51 broadly claims the two-step acid etching process including a first step of removing a native oxide layer by contact with a first acid solution with minimum consumption of said titanium metal and a second step of uniformly acid etching with a second acid solution. Claim 51 does not specifically recite the components of the first and second acid solutions.

the same as the surface produced by the two-step acid etching process called for in claim 51.

Once a prima facie case of anticipation has been established, the burden shifted to Appellants to prove that the prior art product does not necessarily or inherently possess the characteristics of the claimed product. *In re Best*, 562 F.2d 1252, 1255 (CCPA 1977) (“Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product.”) *see also In re Spada*, 911 F.2d 705, 708-09 (Fed. Cir. 1990).

Dr. Gubbi, in his declaration, compared the Osseotite® surface, resulting from treatment of a CP titanium dental implant by contact with an aqueous hydrofluoric acid solution to remove the native oxide layer and subsequent etching with a mixture of sulfuric and hydrochloric acids, to the surfaces of a CP titanium implant resulting from the two-step procedure described in Haruyuki (Facts 10, 11). Dr. Gubbi concluded that the resulting surfaces of Haruyuki “do not resemble” the Osseotite® surface (Fact 12). While Dr. Gubbi attested that the surfaces are different, Dr. Gubbi did not measure the peak-to-valley heights of the resulting Haruyuki surfaces.⁶

⁶ See Oral Hearing Transcript at 8, ll. 7-12:

JUDGE HORNER: What about the peak to valley height not greater than 10 microns?

MS. BAIQ: I don’t think Dr. Gubbi measured that. I’m not sure why.

Further, Gubbi's statements compared the surfaces resulting from Haruyuki's examples to the Osseotite[®] surface resulting from the use of hydrochloric and sulfuric acids for the second acid solution in the acid etching step (Facts 10-12). Claim 51, however, is not limited to this second acid solution. Thus, while the roughened surfaces resulting from Haruyuki's method may differ in appearance from the surface resulting from Appellants' preferred embodiment, Dr. Gubbi's declaration does not show that the prior art surfaces differ structurally from the roughened region resulting from a two-step acid etching method as broadly claimed.

Appellants also argue that Niznick and Haruyuki teach away from their combination. App. Br. 18. The Examiner determined that "Niznick teaches that it was known in the art to have different regions of roughness" and that "Niznick does not teach away from the claimed invention because it merely utilizes different roughness criteria from that of Haruyuki or Wennerberg."⁷ Ans. 4, 8. While Niznick discloses more surface roughness in the threaded, middle region than the roughness disclosed in Haruyuki, Niznick discloses that in the self-tapping region, the surface roughness has

JUDGE HORNER: So this evidence doesn't tell us anything one way or the other on the peaks and valley?

MS. BAIO: About peak and valley heights, I don't think so.

⁷ The rejection relies on Haruyuki or Wennerberg as the primary reference. We are persuaded by Appellants that the Examiner lacked an adequate basis for finding that the surfaces of Wennerberg's implants are the same structure as the roughened surface achieved with the claimed two-step acid etching process. App. Br. 16-17. As such, we do not rely on Wennerberg in our affirmation of the rejection of claim 51.

an average peak-to-valley distance of “up to 20 microns.” (Facts 8, 9). For the reasons provided by the Examiner in the Answer on page 8, line 3 through page 9, line 17 of the Answer, we agree that Niznick does not teach away from the proposed combination. As noted in the Answer and *supra*, Haruyuki provides evidence that use of peak-to-valley dimensions of 10 microns or less were known in the art for the purpose of cell attachment and ongrowth of bone to implants (Facts 1-3). In fact, the teaching in Haruyuki that a mean pore depth greater than 5 microns can irritate the tissue and may develop to become a trigger for cancer (Fact 5) would have led one of ordinary skill in the art to use Haruyuki’s method on the self-tapping portion of Niznick’s implant to promote bone ongrowth while avoiding potential side effects of larger irregularities.

We now consider Appellants’ evidence of secondary considerations provided in the Porter Declaration. App. Br., Ex. 10. “For objective evidence of secondary considerations to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the claimed invention.” *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010) (quotation omitted). “Where the offered secondary consideration actually results from something other than what is both claimed and novel in the claim, there is no nexus to the merits of the claimed invention.” *In re Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011) (citation omitted). In this case, the Porter Declaration is presented to show the commercial success of the Osseotite® surface (Fact 13), but the Osseotite® surface is not the subject of claim 51. Rather, claim 51 broadly encompasses a two-step etch process

that results in the claimed surface topography. The offered secondary considerations do not result from what is claimed (Fact 12). Rather, they result from process steps that are narrower than those claimed. Thus, there is no nexus between this evidence and the merits of the invention of claim 51. Based on the foregoing, we conclude that the evidence in favor of obviousness of the subject matter of claim 51 outweighs Appellants' evidence and arguments against obviousness.

Claim 61

Dependent claim 61 is directed to a titanium dental implant in which the roughened region is made using a two-step acid etch process in which a native oxide layer is removed by contact with a first acid solution and a second acid solution of a mixture of sulfuric and hydrochloric acids is applied to create the acid-etched surface.

As we found *supra*, Haruyuki discloses an acid etch process that uses a different second acid solution than the solution called for in claim 61 (Fact 4). Thus, the question is whether the evidence supports the Examiner's finding that the structure resulting from Haruyuki's acid etching process is the same as the structure achieved by the claimed acid etching process. In this case, the weight of the evidence is in favor of Appellants. Dr. Gubbi stated that "the treatments of the Japanese patent application produced surfaces that do not resemble the surface achieved by the methodology of the subject patent application, as shown in Exhibit A" (Fact 12) (comparing the Haruyuki surfaces with Appellants' surface formed using a second acid solution comprised of a mixture of hydrochloric and sulfuric

acids). Thus, we do not sustain the rejection of claim 61 under 35 U.S.C. § 103(a) as unpatentable over Haruyuki or Wennerberg in view of Niznick.
Claims 63-75

Independent claims 63 and 68 call for the irregularities to include “cone-shaped elements.” As we found *supra*, Haruyuki teaches the use of a different second acid etch solution than the solution disclosed in Appellants’ Specification and Haruyuki discloses that the second acid etching step is “to smooth the sharp edges or pointed ends formed on the ridgelines of the micro fine pits generated during the pretreatment” (Facts 4, 6). Based on this disclosure in the prior art, we find no reasonable basis on which the Examiner could find that Haruyuki’s surfaces would inherently be cone-shaped. *Contra* Ans. 5. “Inherency . . . may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.” *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (citations and quotation marks omitted). For this reason, we do not sustain the rejection of claims 63 and 68, or dependent claims 64-67 and 69-75, under 35 U.S.C. § 103(a) as unpatentable over Haruyuki or Wennerberg in view of Niznick.

CONCLUSIONS

The Examiner provided adequate reasoning based on rational underpinnings to explain why one of ordinary skill in the art would have been led to apply the surface treatment method of Haruyuki to the dental implant of Niznick.

The surface treatment method of Haruyuki, when applied to the dental implant of Niznick, would result in a “roughened region including an array of irregularities having peak-to-valley heights not greater than about 10 microns” as called for in claim 51.

The evidence in support of obviousness outweighs the evidence in support of non-obviousness for claim 51.

The surface treatment method of Haruyuki, when applied to the dental implant of Niznick, would not result in a roughened region or an acid-etched surface that is structurally similar to the region or surface that results from the two-step method of removing a native oxide layer and then acid-etching using a mixture of sulfuric and hydrochloric acids, as called for in claim 61.

The Examiner failed to provide a prima facie showing that the surface treatment method of Haruyuki, when applied to the dental implant of Niznick, would result in “irregularities including cone-shaped elements” as called for in claims 63 and 68.

DECISION

We AFFIRM the Examiner’s decision rejecting claims 51, 60, and 62.

We REVERSE the Examiner’s decision rejecting claims 61, and 63-75.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED-IN-PART

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